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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/216,242	12/18/1998	JOHN M. LIPARI	6439.US.O1	1025

7590

04/25/2002

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/216,242

Applicant(s)

Lipari

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 8, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 12, and 14-17 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 12, and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **DETAILED ACTION**

**The request for the extension of time, filing under 1.114 and the preliminary amendment all dated 4-8-02 are acknowledged.**

**Claims included in the prosecution are 1, 3-5, 12, 14-17.**

#### ***Claim Rejections - 35 U.S.C. § 102***

**1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**2. Claims 1, 3-5, 12 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lacy (5,645,856).**

**Lacy discloses capsules containing emulsions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a cosolvent; the composition further contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7).**

**Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again center around 'structured lipid'. According to applicant, capric and/or caprylic triglycerides taught by Lacy are not structured lipids.**

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These arguments are not found to be persuasive. Applicant's statement on page 3 of the specification is as follows: "Representative structured lipids include, but not limited to, caprylic/capric/lauric triglycerides, e.g., Captex 350<sup>TM</sup> (Abitec) and caprylic/capric/linoleic triglycerides, e.g., Captex 810 series (Abitec) and Miglycol 818 (creanova), and in general, include those lipids containing saturated medium and long chain fatty acids esterified to the same glycerol molecule". As already pointed out before, Lacy on col. 9, lines 20-28 teaches several triglycerides under the trade names Myglycol and Captex and these come under the broad and vague definition given by applicant for a 'structured lipid'. It would appear that Lacy's teachings do not exclude structured lipids. Furthermore, the examiner cites the references of Chavkin (5,753,255) which teaches capric triglyceride as a structured lipid and that of Kikuchi (5,506,230) MCTs as structured lipids are cited as interest (note col. 1, line 58 through col. 2, line 9 of Chavkin; col. 2, lines 24-34 of Kikuchi). The US patent referred to by applicant has been carefully reviewed. Example 1 referred to by applicant just lists the differences in the fatty acid content of various oils and it is unclear to the examiner how this is pertinent to the issue raised.

Applicant's introduction of the term, 'consisting essentially of' is noted. This amendment will not overcome the rejection because "the phrase does not necessarily limit the claims so as to exclude other things when the specification clearly indicates that other constituents may be present" (Ex parte Bonkidis, POBA 1966, 154 USPQ 444). Where the reference composition contains modifying components in addition to those of the claimed

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composition, the exclusion of such components by the phrase “consisting essentially of” does not impart patentability to the composition unless their omission results in a substantial change in the properties of the composition, because the phrase permits the inclusion of ingredients which do not materially affect the basic and novel characteristics of the claimed composition. In re Janakirama-Rao (CCPA 1963) 317 F2d 901, 137 USPQ 893; In re Hertz et al. (CCPA 1976) 537 F2d 549, 190 USPQ 461). Instant specification clearly indicates that surfactants can be added.

*Claim Rejections - 35 U.S.C. § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-5, 12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacy cited above in view of Babayan (4,952,606) of record, Bistraian (4,871,768), Hylander (NCP, 1995) of record, individually or in combination.

Lacy as pointed out above, discloses capsules containing emulsions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a cosolvent; the composition further contains Capric/caprylic

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triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7). It is unclear however, whether Lacy teaches instant 'structured lipids'.

Babayan teaches that structured lipids do not elevate cholesterol levels when administered (col. 1, lines 43-50).

Bistraian teaches that structured lipids assist in fighting atherosclerotic problems (col. 3, line 64 through col. 4, line 15).

Hyltander discusses the advantages of the structured lipids and emulsions containing these in clinical practice (pages 92-96).

Assuming that Lacy's triglycerides are not structured lipids, it is deemed obvious to one of ordinary skill in the art to use the structured triglycerides instead of the triglycerides taught by Lacy, especially when the drug used is for regulating cholesterol or lipid metabolism, since structured triglycerides have advantages relating to cholesterol and atherosclerosis and other clinical advantages as taught by Babayan, Bistraian and Hyltander respectively.

Applicant's arguments have been fully considered, but are deemed to be moot in view of this new rejection.

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**5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

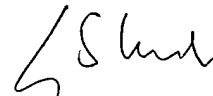
**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is**

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more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**April 22, 2002**